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EXAMINER	
LUCAS, ZACHARIAH	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/663,722	CATES ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 June 2004* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/27/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-20 are pending and under consideration.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on April 27, 2004, is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Specification

3. The disclosure is objected to because of the following informalities:

On page 5, line 14, the specification reads as follows:

> Immunity to these antigens, reduces the likelihood of infections and lessens the severity of the disease if infection occurs.

There should not be a comma after the word "antigens."

On page 21, line 4, the specification reads "Mice were bleed one day prior to the first immunization..." The word "bled" is more appropriate for the sentence structure than "bleed."

Appropriate correction is required.

4. The use of the trademarks "Triton" and "Fluzone" have been noted in this application. These trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Drawings

5. The drawings are objected to because the drawing marked as Figure 1 appears to have indicated the claimed composition as "Flu/RSV + PCP." It appears that this should read - - Flu/RSV + PCPP- -. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions and methods of inducing an anti-RSV immune response in humans, does not reasonably provide enablement for compositions effective for conferring protection or methods of immunizing humans against RSV infection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Claims 1-17 are drawn to compositions "for conferring protection in a host against" RSV caused diseases. Claims 18-20 are drawn to methods for immunizing human hosts against RSV infection.

In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 ¶ 1, the courts have put forth a series of factors. See, In re Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988); and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI 1986). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. Id. While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered. In the present case, those factors considered most relevant

are the breadth of the claims, the presence or absence of working examples, the nature of the invention, the state of the prior art, and the predictability of the art.

As indicated above, the present claims are drawn to compositions for conferring anti-RSV protection, and methods of conferring such protection in humans. The compositions claimed, or used in the claimed methods, comprise subunit formulations of RSV antigens, non-virulent influenza preparations, and optionally, an adjuvant.

In support of the claimed inventions, the application provides an example of a composition comprising an inactivated influenza preparation, a combination of RSV subunit antigens, and (optionally) the adjuvant PCPP. See e.g., page 21 (Example 4). The application also demonstrates that these compositions were able to induce an anti-RSV immune response in mice, and lower viral titer in mice upon challenge after composition administration.

However, in contrast to these teachings, the art indicates both that mouse models are not considered to be effective models of RSV infection because they are not fully permissive for RSV infection. See e.g., Crowe, Vaccine 20: S32-S37, at S32. Further, in addition to noted the limitations of the mouse model of RSV infection, the Crowe references also notes other obstacles faced by those in the art attempting to develop anti-RSV vaccines. Id., pages S32-S33. The reference indicates that, because of the indicated obstacles, and in spite of thirty years of attempts to develop such vaccines (as of 2002), there is still not licensed RSV vaccine. See also, Chidgey et al., J Pharm Pharmacol 57: 1371-81, at 1378 (stating that "Nearly half a century of research into RSV infection has failed to yield an effective and safe treatment or immediate prospects of an RSV vaccine."). These teachings therefore illustrate the state of the prior art, and

teach that there are several sources of unpredictability in the art regarding the ability of any particular potential RSV vaccine to actually provide protection against RSV.

In view of these teachings in the art both regarding the uncertainty in the art, and indicating that the mouse model used in the present application is not an accepted model for demonstrating the efficacy of anti-RSV vaccines, the teachings of the present application are not sufficient to enable those in the art to use the claimed inventions for the purposes described in, or in the methods of, the claims. The claims are therefore rejected as exceeding the scope for which an enabling disclosure has been provided.

8. Claims 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This claim is drawn to a genus of immunogenic compositions comprising any mixture of RSV F, G, and M antigens, any non-virulent influenza preparation, and any adjuvant; wherein the combination including the influenza preparation results in enhances anti-RSV immunogenicity compared to that seen in the absence thereof. The claim is rejected as lacking sufficient written descriptive support for compositions comprising any adjuvant or any inactivated influenza preparation with any mixture of the indicated RSV antigens such that the desired anti-RSV enhancement is achieved.

The following quotation from section 2163 of the Manual of Patent Examination Procedure is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus... See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.
>
> A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Thus, when a claim covers a genus of inventions, the specification must provide written description support for the entire scope of the genus. Support for a genus is generally found where the applicant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed.

However, the presence of even multiple species with in a claimed genus does not necessarily demonstrate possession of the genus. See, In re Smyth, 178 U.S.P.Q. 279 at 284-85 (CCPA 1973) (stating "where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus or combination claimed at a later date in the prosecution of a patent application."); and University of California v. Eli Lilly and Co., 43 USPQ2d 1398, at 1405 (Fed Cir 1997)(citing Smyth for support).

In the present case, the applicant has provided one working example of a combination of RSV antigens with an adjuvant and an influenza preparation that results in an enhanced anti-RSV response compared to the response induced by a formulation comprising only the adjuvant and

the RSV antigens. It is noted that the application argues at this effect was surprising. I.e., it would not have been expected by those skilled in the art that addition of influenza to the combination of PCPP and the subunit RSV composition would result in an increased immunogenicity of the RSV composition. App., page 6, lines 2-14. By describing the claimed effects as surprising, the applicant is also saying that there would have been uncertainty in achieving these affects.

Moreover, the application's assertion that the results were surprising are supported by the teachings in the art. For example, the teachings of Insel et al. (Ann N Y Acad Sci 754: 35-47- of record in the April 2004 IDS) indicate that while it is known in the art that there is a potential for immunological interaction among different vaccines such that when combined an enhanced or suppressed immune response would occur, such interactions are actually rarely observed. Page 37. I.e., Insel indicates that achieving either an enhancement or a suppression of vaccine immunogenicity when combined with another vaccine is rare; and that there would therefore be significant uncertainty in achieving such effects.

The Insel reference also indicates that even different antigenic compositions targeting the same pathogen would not necessarily share any such enhancement or suppression when combined with a different set of antigens to the same pathogens. See e.g., Insel, page 36 (describing different results using different Hib antigens with a DTP formulation). Thus, the art indicates that disclosure of enhancement based on combination of one set of RSV and Influenza antigens would not demonstrate that such enhancement would be seen with any combination of Influenza and RSV antigens. Thus, the teachings of Insel provide two basis of uncertainty. The first is a general ground of uncertainty in that it is not known what antigen combinations may

interact immunologically. The second is that, once on combination of pathogen antigens that interact are known, there remains uncertainty as to whether or not other antigens from the same pathogen would also interact.

As indicated above, the applicants have shown this type of interaction to achieve enhanced immunogenicity using only one combination of antigens: that where a specific combination of RSV antigens is combined with the adjuvant PCPP and the FLUZONE® influenza Vaccine. There are no examples of any other species within the claimed structural genus that acheive the same anti-RSV enhancement. In view of the presence of only a single species of the claimed genus, and of the teachings in the art indicating uncertainty in the ability of other species to achieve the same desired effects, the claim is rejected as lacking adequate written description support for any member of the claimed structural genus that results in the desired enhancement of anti-RSV immunogenicity.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is treated as representative. This claim defines a multivalent immunogenic composition comprising an "immunoeffective amount" of both an anti-RSV immunogenic composition, and a non-virulent influenza composition. It is unclear what is meant by an "immunoeffective amount" of these compositions. For example, it is unclear if the claim language requires that the amount referred to is an amount effective for an immunizing

(protective) response, or if the amount referred to is merely sufficient to induce an immunogenic response. It is also unclear how this amount is determined. It is suggested that the phrase "an immunoeffective amount of" be removed from subparts (a) and (b) of the claim, and from claim 18. I.e., it is suggested that claim 1 be amended such that the claim is amended to read on a composition comprising

- - (a) a mixture of purified fusion (F), attachment (G), and matrix (M) protein of RSV,

(b) a non-virulent influenza virus preparation, and- - .

Clarification of the claim language is required.

11. Claims 1-16, 18, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear from the claims and the specification whether the phrase "non-virulent influenza virus preparation" is limited to whole (e.g. attenuated or inactivated) virus or if the phrase may also comprise subunit influenza vaccines (including preparations not derived from influenza virus- e.g., recombinant proteins). In defining what is meant by "non-virulent influenza virus preparation," the specification provides only general characteristics and examples. See, App., p. 9, lines 25-34. It does not state whether the inclusion of the phrase "virus preparation" includes only whole virus preparations or any preparation derived from an influenza virus.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1-3, 6-19 are rejected under 35 U.S.C. 103(a) as being obvious over Cates et al. U.S. Patent 6,020,182 (Cates U.S.- of record in the April 2004 IDS), in view of Smith et al. (U.S. 5,762,939) and Webster et al. (U.S. 5,824,536). As indicated above, the present claims are drawn to an immunogenic composition comprising an anti-RSV immunogenic formulation, and anti-influenza immunogenic formulation, and, optionally, an adjuvant. The anti-RSV formulation is described as comprising a formulation of the RSV M, F, and G proteins. The anti-influenza formulation is described as comprising a non-virulent influenza virus preparation.

Cates teaches an RSV subunit formulation identical to the formulation used as the RSV component of the instantly claimed multivalent vaccine. Cates also teaches that the composition may also comprise an adjuvant, including adjuvants with immunostimulating effects (therefore imparting an enhanced immune response to RSV). Col. 4, lines 6-24. Finally, Cates also teaches the combination of the RSV vaccine with immunogens against other infections, including immunogens against influenza and that the RSV composition may comprise between 1 and 100 μg of the RSV subunit composition. See, e.g. columns 11-16 (showing varying amounts of the RSV from 1 to 100 μg compositions). However, Cates does not teach that the influenza immunogen is a non-virulent influenza virus preparation.

Smith teaches that influenza vaccines licensed at the time the patent was filed comprised inactivated whole (thus non-virulent) or subunit vaccines comprising preparations from three viral strains. Webster teaches that the inactivated influenza vaccine should be in amounts of between 1-50 μg, and in safe and effective amounts as determined by conventional methods (thus rendering obvious the 1-100 μg range of the instant claims). Col. 13, lines 16-28. Thus, it would have been obvious to one of ordinary skill in the art to use such non-virulent influenza compositions in the composition taught by Cates because such influenza preparations were commonly used in influenza vaccines. Therefore, these references render obvious the claimed composition.

In addition to the suggestion of Cates to combine the treatments, there are also additional motivations in the art to combine the RSV and influenza preparations. The art of vaccination recognized the value of combining treatment so as to simplify the vaccination process, as well as the recognized goal of combining antigens recommended for routine administration into a single product. See, e.g. Plotkin, p. 508. As both RSV and influenza both require yearly vaccinations due to the antigenic shifts in the viruses, immunogenic compositions against infection by these viruses are prime candidates for such combination. See, Potash, U.S. Patent 5,911,998, cols. 1-2; and Smith, cols. 2-3.

Motivation to make the combination may be found in the suggestion in Cates to combine the RSV vaccine with an influenza vaccine, and the teaching of Smith that a known influenza immunogen is a multivalent non-virulent influenza virus composition would render the combination obvious to one of ordinary skill in the art in addition to the general trend in the art of simplifying vaccination by combining commonly administered vaccines. See e.g. Plotkin et

al., Vaccines, Third Ed., p. 508 (of record in the April 2004 IDS). Thus, the combination of the RSV subunit vaccine with a non-virulent influenza virus composition would have been obvious to one of ordinary skill in the art.

It is known in the art that combining vaccines may in some instances affect the immunogenicity of the components. Plotkin, p. 509. Therefore one of ordinary skill in the art would know take precautions and perform the experiments necessary to show that the components of any vaccine combination they may make both retain there safety and efficacy. However, while the art recognizes certain cautions when combining vaccines, the art also indicates that methods are known for circumventing many of these problems. See e.g., Insel, Ann N Y Acad Sci, 754: 35-47, at 36-37 (reference 38 in the April 2004 IDS). Furthermore, while the art recognizes that there may be immunological interaction between different vaccines, the art also indicates that such interaction has actually rarely been observed. Insel, page 37 (second full paragraph). In view of these teachings, given that numerous combination vaccines have been successfully made, the frequency with which such combinations are made, and the suggestion in Cates that the combination of RSV and influenza antigens may be made, one of ordinary skill in the art would still have had a reasonable expectation of success in the combination of the RSV composition disclosed by Cates and the indicated inactivated influenza compositions.

The combined teachings of the cited references therefore render the claimed inventions obvious.

14. Claims 1-3, and 6-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cates et al. ("Cates PCT," WO 98/02457- of record in the April 2004 IDS), in view of Smith (supra.) and Webster (supra). The claims are described above.

Cates PCT teaches an RSV subunit formulation identical to the formulation used as the RSV component of the instantly claimed multivalent vaccine. See, claims 2-9, 13, 21, and 23. Cates PCT also teaches that the composition may also comprise an adjuvant. Claim 17. Finally, Cates PCT also teaches the combination of the RSV vaccine with immunogens against other infections, including influenza and that the RSV composition may comprise between 1 and 100 μg of the RSV subunit composition. See e.g., p. 8, and pp. 29 and 31 (Tables 5, 6, and 8, showing varying amounts of the RSV from 1 to 100 μg compositions). However, Cates does not teach that the influenza immunogen is a non-virulent influenza virus preparation. Such influenza preparations are described in Smith and Webster as applied above. Because the teachings of the Cates PCT are nearly identical to those of Cates above, it would have been obvious to one of ordinary skill in the art to combine the Cates PCT reference with the Smith and Webster references for the same reasons as described above with regards Cates above.

15. Claims 1-3, 5-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Cates or Cates PCT, in view of the teachings of Smith and Weber as applied to claims 1, 3, and 6-18 above, and further in view of Payne (Vaccine 16: 92-98- of record in the April 2004 IDS). Claims 1-3, and 6-18 have been described above. Claim 5 describes the composition of claim 1, wherein the composition comprises PCPP (poly-di(carboxylatophenoxy)-phosphazene) as an adjuvant.

The teachings of Cates, Cates PCT, Smith, and Weber have been described above. As indicated above, each of the Cates and the Cates PCT references indicates that the RSV compositions disclosed therein may include an adjuvant. Cates, columns 8-9; and Cates PCT, pages 16-17, and claims 17 and 18. Further, the references also identify polyphosphazenes as potential adjuvants that may be used. Cates, column 4, lines 12-24; and Cates PCT, claim 18. These references do not, however, teach or suggest the use of PCPP as the adjuvant.

Payne teaches the use of PCPP as a potent immunoadjuvant that enhances the immune response against influenza preparations ten fold. See e.g., abstract. In view of the facts that this reference teaches the use of PCPP as a potent influenza antigen, and that the Cates references indicate that this compound (i.e. polyphosphazenes generally) would also be an effective adjuvant for RSV immunogens, those in the art would have been motivated to use, and had a reasonable expectation of success in the use of, PCPP as an adjuvant in the combination compositions suggested by the references described above. The combined teachings of the cited references therefore render the claimed inventions obvious.

16. Claims 1-3, and 6-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Cates or Cates PCT, as applied to claims 1, 3, and 6-18 above, and further in view of Huebner (U.S. Patent 5,612,037- of record in the April 2004 IDS). The claims and the Cates and Cates PCT references have been described above.

As indicated above, the teachings of the Cates references teach an anti-RSV composition according to the present claims, and suggest that such compositions may be combined with

additional antigenic formulations, including anti-influenza compositions. However, the reference does not specifically teach or suggest the use of a non-virulent influenza preparation.

Huebner describes a commercial inactivated influenza vaccine (FLUZONE®) and its administration in a dose of 5 μg. See, Huebner, col. 1, lines 15-18; and col. 7, Table III. Because Cates U.S. teaches the combination of the disclosed RSV immunogenic composition with an influenza immunogen, and as Huebner teaches a known influenza vaccine composition, it would have been obvious to one of ordinary skill in the art to combine the teachings of Cates with Huebner to achieve the claimed composition. The motivation to combine the references and the expectation of success are provided by Cates and the knowledge in the art as described above.

17. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over either of Cates or Cates PCT, in view of Smith and Weber, or in view of Huebner, as applied above, and further in view of Potash (U.S. 5,911,998- of record in the April 2004 IDS). Claim 20 describes a method of immunizing a human against a disease caused by infection by RSV or influenza by administering the claimed composition wherein the host being treated is a human of at least 18 years of age. The teachings of the previously cited references have been described above. While these references do teach the administration of the indicated compositions to humans, the references do not teach or suggest the administration of such compositions specifically to humans of at least 18 years of age.

Potash teaches that RSV injections in children do not result in long lasting immunity and that, as a result, RSV infections recur throughout adult life. Cols. 1-2. Further, the reference additionally teaches that influenza is a major cause of mortality in older adults (see column 1,

line 52, through column 2, line 5). From these teachings, it would have been obvious to those of ordinary skill in the art to use the combined RSV/influenza compositions suggested by the previously cited references to induce anti-RSV and anti-influenza immune responses in these older age groups which are subject to infections and mortality by these viruses. Those in the art would have had a reasonable expectation of success in the use thereof for the same reasons as indicated above. The combined teachings of these references therefore render the claimed inventions obvious.

Double Patenting

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1-3 and 5-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, and 13 of U.S. Patent No. 6,020,182 (Cates, supra), in view of Smith, Webster, Payne, and Potash as described in the rejections of these claims under 35 U.S.C. 103(a) above. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both claiming vaccine

compositions against RSV infections, and the Cates patent teaches that such RSV compositions may be used in combination with other immunogens, including immunogens against influenza. Col. 4, lines 25-34. The application teaches that the embodiments of the non-virulent influenza virus that form a part of the claimed vaccine are known in the art. App., p. 9. The teachings of the Smith, Weber, Payne, and Potash references; and how the combined teachings of such references with those of Cates render the claimed inventions obvious, have been described above.

The present claims therefore read on obvious variants of the compositions described in the patent.

20. Claims 1- 3 and 5-17, are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 6-16 of U.S. Patent No. 6,309,649, in view of Smith, Webster, and Payne. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both claiming vaccine compositions against RSV infections.

The patent teaches, and claims, that RSV compositions such as those included in the presently claimed compositions. Additionally, the patent teaches that the composition may be used in combination with other immunogens, including immunogens against influenza. Col. 4, lines 36-45; claim 13. Further, the patent also teaches the use of PCPP as an adjuvant with the RSV composition. Col. 12, lines 5-10. However, as with the Cates and Cates PCT references applied under 35 U.S.C. 103 above, the claims of the patent do not teach or suggest the specific influenza compositions currently claimed.

As was previously described, Smith and Webster teach a common influenza immunogenic preparation meeting the limitations of the anti-influenza composition described by the present claims. It would have been obvious to those of ordinary skill in the art to use such non-virulent influenza compositions in the composition taught by the 6,309,649 patent for the same reasons indicated with respect to the combination of Smith and Webster with Cates as described above.

Further, the Payne reference teaches that PCPP is an effective adjuvant for influenza vaccines. In view of the fact that the combination of the patent and Payne indicate that PCPP is an effective adjuvant for both antigenic compositions, it would have been obvious to one of ordinary skill in the art to use this adjuvant in the combination vaccine suggested by the combined teachings of the patent, Smith, and Webster.

The present claims therefore describe obvious variants of the compositions and method of the patent.

21. Claims 1-3, 5-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, and 9-11 of copending Application No. 10/467828 in view of the teachings of Cates PCT, Smith, Webster, and Payne. The present claims have been described above. The claims of the copending application are drawn to an immunogenic composition comprising an RSV M protein, and an antigen. Such compositions would include the compositions suggested by the teachings of the Cates PCT, Smith, Webster, and Payne as described above. In view of the teachings of these references, the present claims

represent an obvious species of the genus of RSV M protein compositions claimed by the copending application.

This is a provisional obviousness-type double patenting rejection.

22. Claims 1-3, 5-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2-7, 9, 12-21, 23, 24, and 36 of copending Application No. 10/488241 in view of the teachings of, Smith, Webster, and Payne, and Potash. The present claims have been described above.

The claims of the copending application are drawn to an immunogenic compositions similar to the anti-RSV formulations disclosed in the present claims, and methods of using such to induce an immune response in humans. Additionally, the reference teaches that the compositions may include at least one additional antigen (claim 21), and may include an adjuvant, such as polyphosphazene (claim 18). The specification of the copending application suggests that the additional immunogen may be from another pathogen, including influenza. Page 6, lines 20-26, and teaches that the polyphosphazene adjuvant may be PCPP (page 18, lines 21-25). Thus, the claims of this copending application provide teachings similar to those of the Cates PCT as described above. It would therefore have been obvious to those of ordinary skill in the art to combine these teachings with those of the Smith, Webster, Payne, and Potash references with this copending application for substantially the same reasons as described above with respect to the combination of these references with either of Cates or Cates PCT above.

In view of the teachings of these references, the present claims represent an obvious variation to the compositions and methods claimed by the copending application.

This is a provisional obviousness-type double patenting rejection.

23. Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3, 5-14, 20, and 21 of copending Application No. 09/868,177. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application describe a species of the presently claimed invention. The species described by the copending application is limited to embodiments of the claimed invention wherein the influenza composition is that described in Example 3 of the copending application. Because the claims of the copending application are drawn to a species of the present application, and would therefore anticipate the present claims if applied under 35 U.S.C. 102, the present claims are rejected for obviousness type double patenting over the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

24. Some of the above rejections are, in part, based on the specifications of previously issued patents, rather than the claims. In support of the use of this material, the examiner notes the following excerpt from MPEP section 804:

> When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.
>
> The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not

> the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

Thus, the courts have held that it is permissible to use the specification in determining what is included in, and obvious from, the invention defined by the claim on which the rejection is based. This is true even where elements are drawn from the specification describing the claimed invention which are not elements in the claim itself. Thus, the fact that the patent identified above teaches that the claimed RSV vaccine composition may be combined with an influenza composition may be used to reject the current claims even though the patent claims do not suggest such a combination.

Conclusion

25. No claims are allowed.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Z. Lucas 6/16/06/
Patent Examiner